

### REMARKS

This amendment is responsive to the final Office Action mailed on April 10, 2001. It should be noted that claims 13-30 drawn to an election which was not elected have been cancelled without prejudice. This is responsive to the statement in the Office Action indicating that a reply to the final rejection must include cancellation of non-elected claims.

Turning now to the specifics of the Office Action, the objection to claims 4-6 and 7-11 for failing to introduce each claim with the proper article is maintained. It is believed that the amendments made to these claims overcome this ground of rejection. It will be noted that the proper articles have been introduced to each of these claims as suggested by the Examiner. Consequently, it is believed that this ground of rejection has been overcome.

Claims 10, 36 and 40 have been held to be indefinite under 35 USC 112 in the use of the phrases "i.e.," and "e.g.," on the grounds that they render the claims indefinite because it is alleged that it is unclear whether the limitations following the phrase is a part of the claimed invention.

It will be noted that these claims have been amended in each instance to delete the terms "i.e., and e.g.," have been substituted with the term "including". It is believed that this overcomes this ground of rejection cited by the Examiner and makes it clear that the subject matter which had followed the "i.e., and e.g.," is indeed included in the claims. It is believed that this ground of rejection has been overcome.

It is noted with appreciation that certain of the claim rejections under 35 USC 112 have been withdrawn.

Claims 31, 9-10 have been rejected under 35 USC 102 for reasons of record in rejecting claims 1 and 8-10 in the previous Office Action.

A review of the previous Office Action which was mailed on July 31, 2000 discloses that the claims 1 and 8-10 were rejected under 35 USC 102 as being anticipated by Cummins et al., U.S. Patent No. 5,081,010. It was stated that Cummins et al discloses a method of treating virus containing sample using a composition comprising of an alcoholamine, a nonionic surfactant cholic acid and an anionic surfactant for the extraction of herpes simplex viral antigens, see reference 2, columns 3-4. Therefore, Cummins et al is alleged to clearly anticipate the aforementioned claims which recite a method for treating a virus containing sample with a solution containing an anionic surfactant and a nonionic surfactant.

A review of the Cummins reference shows that it discloses in the claims an extraction composition comprising alcoholamines, a nonionic surfactant, cholic acid or its derivatives or salts and an anionic surfactant as noted by the Examiner. In distinction however, the Applicants in this case do not claim or disclose in the specification or claims alcoholamines or cholic acid or its derivatives or salts.

Cummins, on the other hand, does not disclose or claim the use of amphoteric surfactants or denaturants as taught in the present case. The reference fails to teach that the presence of nonionic surfactants with a powerful denaturant such as SDS is moderated in its effect and consequently does not affect the core antigens of the virus but does permit breach of the viral envelope.

As can be seen from the description of the present application page 21, line 12 to page 22, line 2, according to Applicants invention the first component, the anionic surfactant liberates the viral antigen. It is also likely that the anionic surfactant provides the denaturing effects on the other components. We believe that the second and/or third components, i.e., non-ionic and amphoteric surfactants reduce or eliminate this secondary denaturing effect on the other components, such as the viral core antigens.

Cummins is also limited in its application to the treatment of one particular virus, herpes simplex virus. There is no way of knowing what the effect of the presence

of the added ingredients of Cummins would have under the denaturation of the core antigens.

Additionally, with reference to columns 9 and 10 of the Cummins patent particularly the hydrogen peroxide solution which contains hydrogen peroxide 10% by weight and diethylenetriaminepentaacetic acid.

The wash solution set forth in column 9 is an aqueous wash solution prepared containing TRITON nonionic surfactant, ethylanolamine hydrochloride and a preservative which is undisclosed.

Turning now to Example 2, it is indicated that the test material on swabs from first patients were placed in an extraction tube and the extraction composition was added. The swabs were swirled in the extraction solution for 1-2 minutes after which the resulting extract was prefiltered through a filtered device. The prefiltered extract was then placed into each well of a test device allowing any HSV antigen to absorb to the membrane in the well. It should be noted however at this point that the test wells were washed with the wash solution noted above and the hydrogen peroxide solution noted above to remove any non specific oxidases. The wells were washed again with the wash solution. The sample of the labeled anti-creatine kinase conjugate in the blocking composition was added to the negative control well of each test device. A sample of the anti-HSV conjugate was added to the other two wells of each device.

After five minutes incubation at room temperature to allow antibody-antigen complexation, the wells were washed twice with the wash solution described above then the wells were treated with a dye composition which indicated the presence of the HSV antigen.

From this, it can be determined that these test materials were not just simply extracted but were subsequently treated with additional nonionic surfactants together with ethylanoamine hydrochloride not once, but many times and were treated at

least once with the diethylenetriaminepentaacetic acid and hydrogen peroxide and an undisclosed preservative.

The teachings of the Cummins reference must therefore be taken into account with this example and this subsequent repetitive treatment of these additional ingredients.

For these reasons, it is respectfully submitted that the Cummins reference does not anticipate claims 31 and 9 and 10 and respectfully requests that this ground of rejection be withdrawn as it neither teaches nor suggests Applicants invention.

However, it will be noted that claim 31 has been amended to include the amounts of the anionic and non-ionic surfactants. It is believed that this further distinguishes these claims over Cummins.

Claims 4, 9-11 and 31-41 have been rejected under 35 USC 103(a) as being obvious and unpatentable over Sharma in view of Kokai and Cloyd.

Before turning to this ground of rejection under the same heading, it has been noted that the application currently names joint inventors. It is stated that in considering the patentability of the claims under 35 USC 103(a) the Examiner presumes that the subject matter of the various claims was commonly owned at the time any invention covered herein was made absent evidence to the contrary. Applicant has been advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 USC 103(c) and potential 35 USC 102(f) or (g) prior art under 35 USC 103(a). Applicants attorney believes that the Examiner's assumption is correct, and he has been assured by a representative of the Applicants that the subject matter of all claims was commonly owned at the time the invention was made.

It may be helpful to review the references which have been combined in this ground of rejection.

Sharma teaches a process for disinfecting biological fluids and blood is one of the more important biological fluids to be disinfected by Sharma.

Blood and the disinfecting composition are mixed. The blood cells are extracted and separated, then the serum is extracted to remove the disinfecting compounds. The cellular components of the blood are then returned to the serum and this can be used for a transfusion. It is extremely important to note that red cell lysine is controlled through the addition of a sugar which, it is noted, appears to be a critical element in this particular type of disinfection and yet it is not included in the claims.

The purpose of Sharma cannot be ignored. It is to kill all bacteria and viruses in a blood sample. Sharma desires to completely destroy virus and bacterial cells. It is a success if the core antigens are destroyed as illustrated by virology tests and culturing.

Sharma treats whole blood. The composition does not damage the blood cells not because of some function of the detergents but rather because of the presence of sugar. See page 18 of Sharma. The concern of Sharma is that the laboratory personnel will not be infected by test samples or routine tests. Sharma is not interested in determining if the samples contain viruses. Sharma only tests to be sure that they have all been killed. The core antigens have been destroyed thereby the sample is a negative result.

This is totally different from the present invention. Here the combination of detergents is designed to rupture the cell wall or the envelope of the virus but not to destroy the core antigens as if present, they would give a positive test to the presence of the virus.

Sharma separates the blood cells and removes the detergents and then mixes the serum in the cells for a transfusion. In this case, the blood cells are not protected. Hemoglobin has been removed by urea. Sharma does not teach the presence of an amphoteric surfactant in the composition. The teaching of Sharma is in opposition to the teaching of this invention and the application of this reference it is respectfully submitted is totally inappropriate for combination with other references.

It must also be noted that Sharma teaches the use of a composition containing an anionic surfactant and at least one nonionic surfactant with a stabilizer. Sharma does not teach a treatment solution comprising an anionic surfactant and an amphoteric surfactant and a nonionic surfactant or a protein denaturant. In fact, this would seem to run counter to the desires of what Sharma is teaching. He does not wish to have the core antigens preserved. He wants everything to be killed and if it gives a negative test, he takes that as evidence that the virus has been destroyed. It also should be noted that in respect to blood serum, any heme from hemoglobin from red cells in the serum in the present invention have to be inactivated through the use of urea otherwise the test for the antigens can be compromised.

Turning now to the Kokai reference, Japanese Patent Abstract No. 53-104724, the purpose of Kokai is to prepare globular uniform particles of a surface antigen of hepatitis virus B (HBsAg). The HBsAg globular particles are prepared to be used as a raw material of serum hepatitis vaccine and is indicated as a standard antigen reagent.

This is done by treating the HBsAg in the presence of a nonionic surface active agent and a protein denaturing agent such as urea or guanidine and it is exposed to a heat treatment.

It is clearly noted that this is not the same use to which the present Applicants put their invention.. It is not to isolate the antigen as such for purposes of vaccines and it is noted further that Kokai does not disclose the use of a nonionic surface

active agent in combination with an anionic surface active agent or an amphoteric surface active agent as taught in the present application.

It is further noted that the Kokai reference is a very brief abstract of two paragraphs taken from a much longer patent in Japanese. It is difficult to fully address and note the distinctions in this reference from the abstract.

Now turning to the Cloyd reference. It is noted that the Cloyd reference has as his use, formation of a nondenaturated HIV envelope antigen for detecting early HIV specific antibodies. While limited in its application, it is noted that this is in essence the same general purpose that Applicants have in preparing samples.

Cloyd uses a composition which singly utilized some six surfactants including anionic surfactants, nonionic surfactants and amphoteric surfactants. It must be noted however, that only one of these is used at any given time. Cloyd does not teach the use of combinations of surfactants or necessarily other materials such a denaturing agents used by Applicants in combination with surfactants.

Of these some six surfactants used individually, only one of the which was found to be fully successful and one of which was found to be partially successful. It must be noted that the nonionic surfactant used MP40 was the ingredient used in the composition which gave only partially satisfactory results. It should also be noted that the fully effective ingredients was digitonen which is used commercially in the determination of cholesterol in blood plasma (see Merck Index 10<sup>th</sup> edition, compound 31, 41 on pages 458 and 459 (1983). If digitonen is a surfactant, it must be considered to be a nonionic surfactant but Applicants are not certain that it is a surfactant. It appears to be a glycoside. Accordingly, Applicants believe that the Cloyd reference teaches only that one nonionic surfactant was partially effective and the only effective compound was the digitonen. All the other detergents tested were ineffective.

Turning now to the Examiner's rejection in detail, it is stated on pages 5 and 6 of the Office Action under paragraph 4, that Sharma discloses a composition of a method of use for disinfecting blood and discloses that the method is useful for preparation of samples for laboratory testing. Said compositions contain at least one nonionic surfactant and a stabilizer. Sharma differs from the claimed invention in that he does not disclose the use of a combination of surfactants, i.e., non-ionic, anionic and amphoteric. Kokai discloses the use of non-ionic surfactants and protein denaturing agents (urea) the removal of HBV antigens from blood samples. Cloyd et al discloses the treating of HIV infected sera with a variety of amphoteric surfactants, non-ionic surfactants, anionic surfactants and protein denaturing agents. Additionally, Cloyd et al discloses the aforementioned agents inactivated the viral agents in the sample since they were non-reactive to HIV specific antibodies. Consequently, the Examiner has held that it would have been obvious to one skilled in the art to use the combination of surfactants disclosed by Cloyd and Kokai in the method disclosed by Sharma since the combinations of the various surfactants and protein denaturing agents would enhance the effectiveness of the Sharma's method of disinfecting samples for the use in laboratory tests since their effects would be additive. Additionally, Kokai discloses the use of disclosed reagents result a material that can be used as a raw material for a vaccine and a standard antigen reagent. Consequently, all the limitations of the instant invention are encompassed by the combination of the cited references. Applicant is reminded that the aforementioned rejection is based on a combination of all the cited references.

In response, Applicant would note that the present invention is a composition for treatment of sera to detect and/or measure the presence of viruses. Only the Cloyd reference has the same purpose. Kokai wishes to extract the use of globular foam of antigens for use in a vaccine and Sharma, as it has been noted, wishes to disinfect, i.e., kill or any virus or bacteria present in biological fluids such as blood. Applicants contend that the different uses and different classifications of these references are such that it would not be suggested to one skilled in the art to combine these



references for any purposes. The teaching of Cloyd shows that while he used some six surfactants and a variety at that only two give positive results. The remainder give negative results and of the two positive, only one (a non-ionic surfactant), gives only partially effective results. This would certainly teach away from the teaching of Sharma that claims the use of a non-ionic surfactant. The one component, the digitonin, is certainly not disclosed in Sharma or in any of the other references that Applicants have been able to find.

• The Examiner's position that since four of the compounds including amphoteric and anionic surfactants were tested by Cloyd and found ineffective because they gave negative results. Those negative results showed that they disinfected, i.e., killed off the virus. It also showed it destroyed the antigens and they could not be tested for positive virus presence. This is contrary to the teaching of the present invention. The results of contrary to the teaching of Cloyd. Neither Kokai or Cloyd provide any basis whatsoever for the combination with Sharma. The disinfection would keep tests from being performed on the blood samples because the core antigens would be destroyed. What it would show is there is no virus or bacteria remaining. This was not only simply done by antigen tests but also by culturing.

It should also be noted that while Sharma wishes to protect laboratory personnel who conduct tests on the sera, those tests were indicated to be routine tests or customary tests. See page 3, lines 27-30 of Sharma.

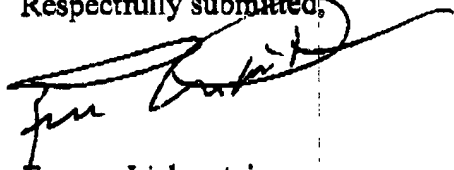
The Examiner in formulating this combination obvious rejection is taking the negative teaching of one patent Cloyd and applying it to the teaching of Sharma. The negative teachings of Cloyd teach away from using this in the invention of Cloyd. The Examiner assumes that since this is negative and it kills at least the virus cells, although not necessarily the bacterial cells, and further destroys the ability of the core antigens to give a positive test then everything negative disclosed in Cloyd can be applied in Sharma in order to justify a combination reference. With the greatest respect, Applicants suggest

that this is disingenuous and reverse thinking. The patent references are used for different things. They have different teachings. They have different teachings with the exception of Cloyd different from that of Applicant. Applicants submit to the Examiner that this ground of rejection fails, that the combination of references is totally inappropriate and requests that this ground of rejection be withdrawn and the claims so rejected be allowed.

It is submitted that such claims are in condition for allowance and such action is respectfully requested.

Because of the lateness of time and the request for extension Applicants have filed a Notice of Appeal with this amendment.

Respectfully submitted,

  
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#### MAILING CERTIFICATE

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Date: October 5, 2001

#### AMENDED CLAIMS

4. (Twice Amended) The [A] method according to claim 31, wherein said treatment solution further contains urea, an imidazole ring-containing compound or an indole ring-containing compound.

9. (Twice Amended) The [A] method according to claim 31, wherein said virus is a virus which forms virus particles having a structure comprising a structural protein encapsulating genomic RNA or DNA and a membrane protein or lipid membrane surrounding it.

10. (Twice Amended) The [A] method [as in] of claim 9, wherein said virus is selected from the group consisting of hepatitis C virus [(i.e.,) including HCV[]], hepatitis D virus, hepatitis E virus, hepatitis G virus, hand-foot-and-mouth disease virus, a flavivirus [(e.g.,) including yellow fever virus, West Nile virus, Japanese encephalitis virus, dengue virus[]], a togavirus [(e.g.,) including alpha-virus, rubivirus, arterivirus, rubella virus[]] a pestivirus [(e.g.,) including hog cholera virus, bovine diarrhea virus[]], a paramyxovirus [(e.g.,) including parainfluenza virus, measles virus, mumps virus[]], an orthomyxovirus [(e.g.,) including human influenza virus, avian influenza virus, equine influenza virus, swine influenza virus[]], a rhabdovirus [(e.g.,) including rabies virus, vesicular stomatitis virus[]], a picornavirous [(e.g.,) including poliovirus, Coxsackie virus, echovirus, bovine enterovirus, porcine enterovirus, simian enterovirus, mouse encephalitis virus, human rhinovirus, bovine rhinovirus, equine rhinovirus, foot and mouth disease virus, hepatitis A virus[]], a coronavirus [(e.g.,) including human coronavirus, avian infectious bronchitis virus, mouse hepatitis virus, porcine transmissible gastroenteritis virus[]], an arenavirus [(e.g.,) including lymphocytic choriomeningitis virus, lassa virus, Korean hemorrhagic fever virus[]], a retrovirus [(e.g.,) including HTLV: human adult leukemia virus, HIV: AIDS virus, feline leukemia sarcoma virus, bovine leukemia virus, Rous sarcoma virus[]], a reovirus [(e.g.,) including rotavirus[]], a calcivirus [(e.g.,) including Norwalk virus[]], a bunyavirus [(e.g.,) including renal syndrome hemorrhagic fever virus[]], a phyllovirus [(e.g.,) including Ebola virus, Marburg virus[]], hepatitis B virus (HBV), a pox virus [(e.g.,) including

vaccinia virus[]], alastrim virus, cowpox virus, smallpox virus, a parvovirus [(e.g.,] including human parvovirus, porcine parvovirus, bovine parvovirus, canine parvovirus, a feline leucopenia virus, Aleutian mink disease virus[]], a papovavirus [(e.g.,] including papilloma virus, polyoma virus[]], adenovirus, a herpes virus [(e.g.,] including herpes simplex virus, cytomegalovirus, chickenpox herpes zoster virus, EB virus, equine herpes virus, feline herpes virus, Marek's disease virus[]] and African swine cholera virus.

11. (Twice Amended) The [A] method according to claim 31, wherein said virus is hepatitis C virus (HCV) or hepatitis B virus (HBV).

31. (Amended) A method for treating a virus-containing sample to obtain a sample suitable for detection of virus by a probe, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution containing (a) at least 0.5% of an anionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant at least 0.1% of, a nonionic surfactant and a protein denaturant; and

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the virus antigen is exposed or released; and antibodies against the virus antigen, if present in the sample, that interfere with a detection reaction, are inactivated, and which sample can be readily subjected to an immunoassay using a probe without affecting the probe.

32. (Amended) A method for treating a virus-containing sample to obtain a sample suitable for detection of virus by a probe, comprising the step of:

(1) treating a virus-containing sample with a treatment solution comprising (a) at least 0.5% of an anionic surfactant, (b) an amphophetic surfactant, and (c) an agent selected from the group consisting of at least 0.1% of a nonionic surfactant and a protein denaturant; and

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and which sample can be readily subjected to an immuno assay using a probe without affecting the probe.

34. (Amended) The [A] method according to claim 32, wherein said treatment solution further contains urea.

35. (Amended) The [A] method according to claim 32, wherein said virus is a virus which forms virus particles having a structure comprising a structural protein encapsulating genomic RNA of DNA and a membrane protein or lipid membrane surround it.

36. (Amended) The [A] method according to claim 35, wherein said virus is selected from the group consisting of hepatitis C virus [(i.e.,) including HCV]], hepatitis D virus, hepatitis E virus, hepatitis G virus, hand-foot-and-mouth disease virus, a flavivirus [(e.g.,) including yellow fever virus, West Nile virus, Japanese encephalitis virus, dengue virus]], a togavirus [(e.g.,) including alpha-virus, rubivirus, arterivirus, rubella virus]], a pestivirus [(e.g.,) including hog cholera virus, bovine diarrhea virus]], a paramyxovirus [(e.g.,) including parainfluenza virus 1, 2, 3, 4, canine distemper virus, Newcastle disease virus, RS virus, rinderpest virus, simian parainfluenza virus, measles virus, mumps virus]], an orthomyxovirus [(e.g.,) including human influenza virus, avian influenza virus, equine influenza virus, swine influenza virus]], a rhabdovirus [(e.g.,) including rabies virus, vesicular stomatitis virus]], a picornavirus [(e.g.,) including poliovirus, Coxsackie virus, echovirus, bovine enterovirus, porcine enterovirus, simian enterovirus, mouse encephalitis virus, human rhinovirus, bovine rhinovirus, equine rhinovirus, foot and mouth disease virus, hepatitis A virus]], a coronavirus [(e.g.,) including human coronavirus, avian infectious bronchitis virus, mouse hepatitis virus, porcine transmissible gastroenteritis virus]], an arenavirus [(e.g.,) including lymphocytic choriomeningitis virus, lassa virus, Korean hemorrhagic fever virus]], a retrovirus [(e.g.,) including HTLV: human adult leukemia virus, HIV: AIDS virus, feline leukemia

sarcoma virus, bovine leukemia virus, Rous sarcoma virus[]], a reovirus [(e.g.,) including rotavirus[]], a calcivirus [(e.g.,) including Norwalk virus[]], a bunyavirus [(e.g.,) including renal syndrome hemorrhagic fever virus[]], a phyllovirus [(e.g.,) including Ebola virus, Marburg virus[]], hepatitis B virus [(i.e.,) including HBV[]], a pox virus [(e.g.,) including vaccinia virus, alastrim virus, cowpox virus, smallpox virus[]], a parvovirus [(e.g.,) including human parvovirus, porcine parvovirus, bovine parvovirus, canine parvovirus, feline leucopenia virus, Aleutian mink disease virus[]], a papovavirus [(e.g.,) including papilloma virus, polyoma virus[]], adenovirus, a herpes virus [(e.g.,) including herpes simplex virus, cytomegalovirus, chickenpox herpes zoster virus, EB virus, equine herpes virus, feline herpes virus, Marek's disease virus[]] and African swine cholera virus.

37. (Amended) The [A] method according to claim 32, wherein said virus is selected from the group consisting of hepatitis C virus (HCV) and hepatitis B virus (HBV).

38. (Amended) The [A] method according to claim 33, wherein said treatment solution further contains urea.

39. (Amended) The [A] method according to claim 35, wherein said virus is a virus which forms virus particles having a structure comprising a structural protein encapsulating genomic RNA or DNA and a membrane protein or lipid membrane surrounding it.

40. (Amended) The [A] method according to claim 39, wherein said virus is selected from the group consisting of hepatitis C virus is selected from the group consisting of hepatitis C virus [(i.e.,) including HCV[]], hepatitis D virus, hepatitis E virus, hepatitis G virus, hand-foot-and-mouth disease virus, a flavivirus [(i.e.,) including yellow fever virus, West Nile virus, Japanese encephalitis virus, dengue virus[]], a togavirus [(e.g.,) including alpha-virus, rubivirus, arterivirus, rubella virus[]], a pestivirus

[(e.g.,) including hog cholera virus, bovine diarrhea virus[]], a paramyxovirus [(e.g.,) including parainfluenza virus 1, 2, 3, 4, canine distemper virus, Newcastle disease virus, RS virus, rinderpest virus, simian parainfluenza virus, measles virus, mumps virus[]], an orthomyxovirus [(e.g.,) including human influenza virus, avian influenza virus, equine influenza virus, swine influenza virus[]], a rhabdovirus [(e.g.,) including rabies virus, vesicular stomatitis virus[]], a picornavirus [(e.g.,) including poliovirus, Coxsackie virus, echovirus, bovine enterovirus, porcine enterovirus, simian enterovirus, mouse encephalitis virus, human rhinovirus, bovine rhinovirus, equine rhinovirus, foot and mouth disease virus, hepatitis A virus[]], a coronavirus [(e.g.,) including human coronavirus, avian infectious bronchitis virus, mouse hepatitis virus, porcine transmissible gastroenteritis virus[]], an arenavirus [(e.g.,) including lymphocytic choriomeningitis virus, lassa virus, Korean hemorrhagic fever virus[]], a retrovirus [(e.g.,) including HTLV: human adult leukemia virus, HIV: AIDS virus, feline leukemia sarcoma virus, bovine leukemia virus, Rous sarcoma virus[]], a reovirus [(e.g.,) including rotavirus[]], a calcivirus [(e.g.,) including Norwalk virus[]], a bunyavirus [(e.g.,) including renal syndrome hemorrhagic fever virus[]], a phyllovirus [(e.g.,) including Ebola virus, Marburg virus[]], hepatitis B virus [(i.e.,) including HBV[]], a pox virus [(e.g.,) including vaccinia virus, alastrim virus, cowpox virus, smallpox virus[]], a parvovirus [(e.g.,) including human parvovirus, porcine paravovirus, bovine parvovirus, canine parvovirus, feline leucopenia virus, Aleutian mink disease virus[]], a papovavirus [(e.g.,) including papilloma virus, polyoma virus[]], adenovirus, a herpes virus [(e.g.,) including herpes simplex virus, cytomegalovirus, chickenpox herpes zoster virus, EB virus, equine herpes virus, feline herpes virus, Marek's disease virus[]] and African swine choler virus.

41. (Amended) The [A] method according to claim 33, wherein said virus is selected from the group consisting of hepatitis C virus (HCV) and hepatitis B virus (HBV).

## CLAIMS

4. The method according to claim 31, wherein said treatment solution further contains urea, an imidazole ring-containing compound or an indole ring-containing compound.

9. The method according to claim 31, wherein said virus is a virus which forms virus particles having a structure comprising a structural protein encapsulating genomic RNA or DNA and a membrane protein or lipid membrane surrounding it.

10. The method of claim 9, wherein said virus is selected from the group consisting of hepatitis C virus including HCV, hepatitis D virus, hepatitis E virus, hepatitis G virus, hand-foot-and-mouth disease virus, a flavivirus including yellow fever virus, West Nile virus, Japanese encephalitis virus, dengue virus, a togavirus including alpha-virus, rubivirus, arterivirus, rubella virus a pestivirus including hog cholera virus, bovine diarrhea virus, a paramyxovirus including parainfluenza virus, measles virus, mumps virus, an orthomyxovirus including human influenza virus, avian influenza virus, equine influenza virus, swine influenza virus, a rhabdovirus including rabies virus, vesicular stomatitis virus, a picornavirous including poliovirus, Coxsackie virus, echovirus, bovine enterovirus, porcine enterovirus, simian enterovirus, mouse encephalitis virus, human rhinovirus, bovine rhinovirus, equine rhinovirus, foot and mouth disease virus, hepatitis A virus, a coronavirus including human coronavirus, avian infectious bronchitis virus, mouse hepatitis virus, porcine transmissible gastroenteritis virus, an arenavirus including lymphocytic choriomeningitis virus, lassa virus, Korean hemorrhagic fever virus, a retrovirus including HTLV: human adult leukemia virus, HIV: AIDS virus, feline leukemia sarcoma virus, bovine leukemia virus, Rous sarcoma virus, a reovirus including rotavirus, a calcivirus including Norwalk virus, a bunyavirus including renal syndrome hemorrhagic fever virus, a phyllovirus including Ebola virus, Marburg virus, hepatitis B virus (HBV), a pox virus including vaccinia virus, alastrim virus, cowpox virus, smallpox virus, a parvovirus including human parvovirus, porcine parvovirus, bovine parvovirus, canine parvovirus, a feline leucopenia virus, Aleutian mink disease virus, a papovavirus including papilloma virus, polyoma virus, adenovirus,



a herpes virus including herpes simplex virus, cytomegalovirus, chickenpox herpes zoster virus, EB virus, equine herpes virus, feline herpes virus, Marek's disease virus and African swine cholera virus.

11. The method according to claim 31, wherein said virus is hepatitis C virus (HCV) or hepatitis B virus (HBV).

31. A method for treating a virus-containing sample to obtain a sample suitable for detection of virus by a probe, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution containing (a) at least 0.5% of an anionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant at least 0.1% of, a nonionic surfactant and a protein denaturant; and

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the virus antigen is exposed or released; and antibodies against the virus antigen, if present in the sample, that interfere with a detection reaction, are inactivated, and which sample can be readily subjected to an immunoassay using a probe without affecting the probe.

32. A method for treating a virus-containing sample to obtain a sample suitable for detection of virus by a probe, comprising the step of:

(1) treating a virus-containing sample with a treatment solution comprising (a) at least 0.5% of an anionic surfactant, (b) an amphophetic surfactant, and (c) an agent selected from the group consisting of at least 0.1% of a nonionic surfactant and a protein denaturant; and

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and which sample can be readily subjected to an immuno assay using a probe without affecting the probe.

34. The method according to claim 32, wherein said treatment solution further contains urea.

35. The method according to claim 32, wherein said virus is a virus which forms virus particles having a structure comprising a structural protein encapsulating genomic RNA of DNA and a membrane protein or lipid membrane surround it.

36. The method according to claim 35, wherein said virus is selected from the group consisting of hepatitis C virus including HCV, hepatitis D virus, hepatitis E virus, hepatitis G virus, hand-foot-and-mouth disease virus, a flavivirus including yellow fever virus, West Nile virus, Japanese encephalitis virus, dengue virus, a togavirus including alpha-virus, rubivirus, arterivirus, rubella virus, a pestivirus including hog cholera virus, bovine diarrhea virus, a paramyxovirus including parainfluenza virus 1, 2, 3, 4, canine distemper virus, Newcastle disease virus, RS virus, rinderpest virus, simian parainfluenza virus, measles virus, mumps virus, an orthomyxovirus including human influenza virus, avian influenza virus, equine influenza virus, swine influenza virus, a rhabdovirus including rabies virus, vesicular stomatitis virus, a picornavirus including poliovirus, Coxsackie virus, echovirus, bovine enterovirus, porcine enterovirus, simian enterovirus, mouse encephalitis virus, human rhinovirus, bovine rhinovirus, equine rhinovirus, foot and mouth disease virus, hepatitis A virus, a coronavirus including human coronavirus, avian infectious bronchitis virus, mouse hepatitis virus, porcine transmissible gastroenteritis virus, an arenavirus including lymphocytic choriomeningitis virus, lassa virus, Korean hemorrhagic fever virus, a retrovirus including HTLV: human adult leukemia virus, HIV: AIDS virus, feline leukemia sarcoma virus, bovine leukemia virus, Rous sarcoma virus, a reovirus including rotavirus, a calcivirus including Norwalk virus, a bunyavirus including renal syndrome hemorrhagic fever virus, a phyllovirus including

Ebola virus, Marburg virus, hepatitis B virus including HBV, a pox virus including vaccinia virus, alastrim virus, cowpox virus, smallpox virus, a parvovirus including human parvovirus, porcine parvovirus, bovine parvovirus, canine parvovirus, feline leucopenia virus, Aleutian mink disease virus, a papovavirus including papilloma virus, polyoma virus, adenovirus, a herpes virus including herpes simplex virus, cytomegalovirus, chickenpox herpes zoster virus, EB virus, equine herpes virus, feline herpes virus, Marek's disease virus and African swine cholera virus.

37. The method according to claim 32, wherein said virus is selected from the group consisting of hepatitis C virus (HCV) and hepatitis B virus (HBV).

38. The method according to claim 33, wherein said treatment solution further contains urea.

39. The method according to claim 35, wherein said virus is a virus which forms virus particles having a structure comprising a structural protein encapsulating genomic RNA or DNA and a membrane protein or lipid membrane surrounding it.

40. The method according to claim 39, wherein said virus is selected from the group consisting of hepatitis C virus is selected from the group consisting of hepatitis C virus including HCV, hepatitis D virus, hepatitis E virus, hepatitis G virus, hand-foot-and-mouth disease virus, a flavivirus including yellow fever virus, West Nile virus, Japanese encephalitis virus, dengue virus, a togavirus including alpha-virus, rubivirus, arterivirus, rubella virus, a pestivirus including hog cholera virus, bovine diarrhea virus, a paramyxovirus including parainfluenza virus 1, 2, 3, 4, canine distemper virus, Newcastle disease virus, RS virus, rinderpest virus, simian parainfluenza virus, measles virus, mumps virus, an orthomyxovirus including human influenza virus, avian influenza virus, equine influenza virus, swine influenza virus, a rhabdovirus including rabies virus, vesicular stomatitis virus, a picornavirus including poliovirus, Coxsackie virus, echovirus, bovine enterovirus, porcine enterovirus, simian enterovirus, mouse encephalitis virus, human rhinovirus, bovine rhinovirus, equine rhinovirus, foot and

החלטת הוועדה להעביר את המסמך למשרד המשפטים, להחליט על הפיקוח והאחריות על המסמך, ולקבוע את המסגרת המשפטית והאחריות.

41. The method according to claim 33, wherein said virus is selected from the group consisting of hepatitis C virus (HCV) and hepatitis B virus (HBV).